

The Maryland Board of Pharmacy Public Meeting September 15, 1999

President Stanton Ades called the public meeting to order at 8:46 A.M.

In attendance were President Stanton Ades, Commissioners: W. Irving Lottier, Wayne Dyke, Ramona McCarthy Hawkins, Melvin Rubin, Barbara Faltz Jackson, Jeanne Furman, Laura Schneider and Dr. Raymond Love ; Board Counsel, Paul Ballard; Board Staff, Executive Director, Norene Pease; PCO, Michelle Andoll, PCO Assistant Dorothy Levi and Secretary, Wendy Wilson, and PEP Student, Neil Smith.

Commissioners absent were: Rev. William Johnson, David Russo and Donald Yee

Guests present: Tiffany Corun, Randy R. Delker, Neil Smith, Mike Nicholson, Michael Johansen, Nathan Gruz, Kathryn Lavriha, Ray Haisl, Jack Freedman and Cathy Putz.

Recusals

President Ades asked if any member of the Board who has a conflict of interest relating to any item on the agenda should notify the Board at this time.

None

Approval of Minutes

Page one (1), under approval of minutes, first sentence, should read, a motion, instead of a motioned; page five (5), third paragraph, fourth sentence change were to where, and fifth sentence, change agencies to agency, same page, fourth paragraph, last sentence, change states to state; same page last paragraph, sixth line, delete the word compromising; page nine (9), third paragraph, last sentence, delete *the* from focus on reducing; page ten (10), first paragraph, first sentence change from “do to a relocation” to “due to a relocation”, same paragraph, change sentence beginning with PCS to read, PCS currently has a Short Term Request Policy which states, “When a patient is in need of a local supply of medication, PCS allows the patient to obtain a thirty (30) day supply at the pharmacy of their choice.

A motion was made by Ms. Jackson to approve August 18, 1999 minutes as amended. The motion was seconded by Dr. Love, with a unanimous decision from the Board.

Executive Director's Report/Executive Committee Report

Ms. Pease reminded the Board members of the Executive Officer's Conference, that will take place on September 26-29, 1999 in Washington, D.C.. Ms. Pease reported that, thus far, she has received confirmation for attendance from President Ades, Ms. Schneider, Mr. Yee and Mr.

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Rubin. Ms. Pease stated that she has the necessary information regarding this conference, if any other members of the Board would like to attend. Ms. Jackson stated that she could only attend on Sunday, September 26, 1999.

Ms. Pease reported that presentations from the Board on Internet Pharmacy and Pharmacy Support Staff would be made at a Joint Legislative Committee Hearing on October 12, 1999. Mr. Rubin and Dr. Love will attend this hearing. Ms. Pease stated that if any other members of the Board would like to attend this hearing, she would obtain information regarding the location and time as soon as possible.

Guest Presenter - Neil Smith - Status of Other States' Regulations Addressing Pharmacy Structures Under Emergency Situations

Mr. Smith stated that he completed a follow up report from the August Board meeting, to ascertain whether establishments in the State of Maryland are temporarily placing trailers on sites while the permanent buildings are under construction. Do other states have existing regulations in place for emergency and/or temporary situations? Mr. Smith reported that a survey was sent to each state, and only thirty-one (31) states responded. Mr. Smith stated that out of thirty-one (31) states that responded, twenty-seven (27) stated that any temporary building site would require an inspection.

Mr. Smith further reported that, according to the survey, most states reported that the emergencies would be handled on a case by case basis. Four (4) of the states place a time limit on obtaining an emergency site, which are: Missouri, Arizona, West Virginia and Ohio. The survey indicated that these states will allow temporary site operation for no more than six (6) months, before applying for a change of location. Mr. Smith stated that most of the states reported that if the temporary site is a trailer, the wheels would have to be removed, and if the temporary site is a modular truck, it would have to be placed on cylinder blocks. Mr. Smith reported that most states would leave the final decision of applying for temporary sites up to the discretion of the Executive Director of each State.

In conclusion, Mr. Smith stated that the definition for emergency was different for all the states that responded to the survey, and suggested that the Board establish regulations that would require inspections on all temporary sites. Mr. Rubin suggested having the Licensing Committee investigate this matter further, to determine how the Board would make its decision.

Board Counsel's Report

None

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Committee Reports

Licensing Committee -

Mr. Dyke reported that there were ten (10) candidates for the reciprocity meeting held on Tuesday, September 14, 1999. The candidates were as follows: Margaret E. Anthon, Gary A. Ashcraft, Christine H. Chung, Nga Doan, Brenda R. Giffin, Franklin Goldman, Muna Nour, Thomas O'Neill, Debra L. Sawyer and Catherine B. Willmore. Mr. Dyke motioned that all candidates be approved with the exception of Brenda R. Giffin, who needed to complete the Oral English Competency Examination and would be licensed once the oral exam has been approved. The motion was seconded by Ms. Jackson, with a unanimous decision from the Board.

Laboratory Examination Update

Mr. Dyke reported on an update of the examination from June 1999, in which one hundred and thirty-eight (138) candidates passed, three (3) were reinstated, thirteen (13) failed, six (6) are pending for their FPGEE certificate. The next Laboratory Examination will be administered on Tuesday, October 12, 1999, at a new temporary building location at the School of Pharmacy. President Ades and Ms. Furman will be proctors for this examination.

Correcting Renewal Year for Oct., Nov., Dec., Birth months -

The Pharmacy Practice Act states that a pharmacist renewing for the first time would not have to submit Continuing Education (CE) credits, and that a pharmacist license can not be issued for more than two years. For that reason, the Board decided that new pharmacist graduates that were first licensed in 1997, who renewed in 1998, to prevent them from receiving a license for more than twenty-four (24) months, would only need CE credits for the months that exceeded the normal twenty-four (24) month cycle, when renewing in 1999. October renewal candidates need to obtain 1.25 CE's, November renewal candidates need to obtain 2.50 and December candidates need to obtain 3.75. Dr. Love motioned to approve the required number of CE's for the months of October, November and December. The motion was seconded by Ms. Jackson, with a unanimous decision from the Board. The Licensing Committee will review the potential future problem caused by the change to renewal by birth month. The next Licensing Committee meeting will be Tuesday, September 21, 1999 at 2:00 p.m., at 4201 Patterson Avenue, Baltimore, MD 21215.

Regulation Update -

Ms. Pease stated that at the August 1999 Board meeting, she announced that Anil Punyapu would

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be the Board's new Legislative Officer. Ms. Pease reported that Mr. Punyapu had to resign his position with the Board due to a conflict of interest. Mr. Punyapu is currently enrolled in law school, and was told that he could not work full time and go to school full time. Ms. Pease reported that the Legislative position has been offered to Ayn Hoyt who will be starting on Wednesday, October 6, 1999.

Comments on Security Regulations -

Ms. Pease reported that the Board received comments from Mr. Michael Johansen, Attorney, on behalf of the National Association of Chain Drug Stores (NACDS), on the proposed regulation 10.34.05, Pharmacy Security. The comments summarized NACDS' concerns and raised questions regarding the wording and meaning of the proposed regulations, in which NACDS feels the wording may need to be clarified before the regulations are adopted in their final form. The intent of the proposed change is to allow a pharmacist to be on the premises of the pharmacy and not to be confined to the counter area of the pharmacy. This being, in case a patient may need counseling or have a pharmaceutical question. On August 31, 1999, Ms. Pease responded to Mr. Johansen's letter, in writing, clarifying and modifying the language of proposed regulation 10.34.05. Dr. Love motioned to approve the change noted by Ms. Pease's August 31, 1999 letter to Mr. Johansen. The motion was seconded by Ms. Hawkins, with a unanimous decision from the Board.

Regulations Status Report - September 1999 -

Ms. Pease submitted to the Board a status report of the Board's pharmacy regulations.

PEAC (Pharmacists Education and Assistance Committee) Update -

Mr. Delker, PEAC representative, stated that the committee has developed a Community Education Program. This program has been ACPE approved. Three students have been selected to participate in this program. Mr. Delker stated that PEAC has hired a Public Relations person to better promote public association with the organization. PEAC has taken on two (2) new committee members and is still hoping to recruit more members.

Pharmacy Practice Committee -

Dr. Love reported that the committee met on September 1, 1999. Mr. Punyapu has been asked to redraft the format of prescriptions regulation which will be presented at the next committee meeting on October 6, 1999, at 4:30, at 4201 Patterson Avenue, Baltimore, MD 21215. Topics of discussion will be, whether confidentiality is a problem in outsourcing, regulations for subcontracting with other pharmacies and who's label would appear on a final product, internet

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pharmacies placing computers in physicians offices, price lists on web-sites, and refill reminder programs. Dr. Love further stated that he received a draft letter referencing health department nurses dispensing the wrong forms of medications, and would like the Board's Pharmacist Compliance Officer (PCO) Michelle Andoll, to investigate this allegation, to see whether this particular error was due to lack of procedures.

Expiration Dating for Investigational Drugs -

Ms. Andoll reported that the Board received a letter from Ms. Traci Baroni, Director of Policies, at the Pharmaceutical Research and Manufacturers of America (PhRMA), stating that she would like the Board's interpretation of the Maryland statutes and regulations requiring expiration dates on drugs dispensed by pharmacist and on manufacturer's labels. In Ms. Baroni's interpretation, expirational drugs should have an expiration date on their labels. Ms. Andoll submitted to the Board her letter of response to Ms. Baroni in which she cited article 12-505. Article 12-505, does not differentiate between investigational and non-investigational drugs, but does require dating on all prescriptions, including investigational drugs. Ms. Andoll stated in her response that it is the practice of good pharmacy to label prescriptions with an expiration date. The expiration date placed on the prescription label has never been required to be the true expiration date or manufacturer's expiration date of the product. Ms. Hawkins motioned to approve Ms. Andoll's response letter to Ms. Baroni. The motion was seconded by Ms. Jackson, with a unanimous decision from the Board.

Maryland Psychiatric Research Center -

The Board received a letter from Ms. Camie P. Smith, of the Maryland Psychiatric Research Center, requesting the Board's approval for a variation on patient identification on prescriptions for research studies, which would include: a pharmacy licensed in the State of Maryland that will compound individual prescriptions for patients in research protocols; the compounded prescriptions to be supplied in vials and labeled with patient numbers; the properly labeled prescriptions to be distributed to pharmacies and licensed prescribers; and, at the end of the study, the compounding pharmacy will receive a list of names that corresponds to the patient numbers, and the compounding pharmacy will maintain these records on-site as prescription records. Dr. Love motioned to approve Ms. Andoll's letter of response to Ms. Smith, which states that the Board would not object to the implementation of the proposed procedures and that these procedures would not be in violation of the Pharmacy Practice Act. The motion was seconded by Ms. Hawkins, with a unanimous decision from the Board.

Unlicensed Personnel Task Force -

Mr. Rubin reported that this committee met on September 9, 1999. The 10.34.10A (Standards of

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Practice-Unlicensed Personnel) regulations have been revised and will be presented to the Board at its next meeting in October 1999. The committee has completed their brochure titled, "The Pharmacy Team and You". This brochure explains how technicians and support personnel operate. Mr. Rubin stated that this brochure will be sent out to every pharmacy permit holder free of charge. Mr. Rubin reported that he has been keeping Delegate Goldwater abreast with all of the committee decisions and work progress.

Automation Task Force -

Dr. Love stated that the committee will meet on September 16, 1999. Dr. Love stated that the areas of controversy are off-site and remote site access for dispensing units. Recommendations will come to the Board for review. They are currently in a rough regulatory form.

Medication Error Prevention Project - First Meeting Date -

Ms. Andoll reported that Mr. David Bushwood, Professor at Florida University, will sponsor a conference titled, Pharmacist Workload: Defining the Problem and Meeting the Challenge, on October 23, 24, 1999, at the Double Tree Resort, 3011 Maingate Lane, Kissimmee, Fl., 34747. Some issues to be addressed are: medication errors, adequate personnel staffing, reasonable pharmacy workload, etc. Ms. Andoll stated that she has information regarding this conference, if any Board members would like to attend.

Conscience Clause Committee - First Meeting Date

The Conscience Clause Committee will meet on Tuesday, September 21, 1999, at 1:00p.m., at 4201 Patterson Avenue, Baltimore, MD 21215.

Public Relations Committee/Counsel of Boards Report -

Committee Review of Media RFPs

Ms. Jackson reported that the committee reviewed five (5) interested firms. The evaluation committee members were: Ms. Furman, Mr. Lottier, Mr. Rubin, Ms. Pease, Ms. Banks, Ms. Jackson and Officer of Contracts, Ms. Theresa Ammons. Final stages of the evaluation occurred Tuesday, September 14, 1999.

Ms. Jackson stated that the criteria of the vendors will be their ability to successfully deliver the following:

1. Develop and implement a publicity campaign promoting the role of the pharmacist

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in preventing illness and injury.

2. Write, produce and publicize the creative materials.
3. Create and be responsible for assimilating the marketing and publicity concepts for current and future years of the campaign.
4. Prepare a budget and perform cost projections.
5. Conduct research and develop a strategic plan for a promotion and publicity campaign.
6. Develop a survey instrument to measure the effectiveness of the campaign.
7. Work closely with the Oversight Committee, Advisory Council and report to the Board of Pharmacy.

Ms. Jackson motioned to have the material of the Media evaluation approved. The motion was seconded by Dr. Love, with a unanimous decision from the Board.

Council of Boards Meeting Report -

Ms. Jackson reported on the September 13, 1999, meeting. The Secretary of the Department has five priorities: Y2K, quality of care, health choice MCO, infrastructure of Department and the subcabinet of health policy.

Ms. Pease reported that Mr. Rubin and Ms. Cornish, Licensing Unit Supervisor, attended the last office space meeting, and was informed that the Board would have first preference to any available space. The next meeting is September 17, 1999, at 12:00 noon. Ms. Pease will attend.

The new Director of Public Relations is Karen Black. Tracy Deshields has changed positions.

Mr. Ballard discussed the Administrative Law Judge's office and the option for the Board to hold hearings there.

Budget Committee - FY 2001 Budget Review and Approval to Cease Funding the Shared Fiscal Analyst and Regulations Coordinator - Tamarra Banks

Ms. Banks submitted to the Board the fiscal years 2001 budget. The budget exceeds the previous fiscal years budget by more than the 5% growth that it is normally allowed. This is due to

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increases in salaries, per diems, instate travel, contractual services, database software and equipment services. Ms. Pease reported that Ms. Banks has designed the current database that the Board uses for licensing and is in the process of designing a database for disciplinary cases. This system will allow integration between licensing and discipline cases. Ms. Jackson motioned for acceptance of the budget presented by Ms. Banks. The motion was seconded by Ms. Hawkins, with a unanimous decision from the Board.

Status of Internet Site - Tamarra Banks -

Ms. Banks stated that she would need to retrieve information from all of the Board's committees in order to be able to design the web pages properly. This information would give details of what each committee would like consumers to have access to from the internet. Ms. Banks stated that one of her objectives is for consumers to have verification access from the internet. Mr. Ballard would need to approve information to be put on the internet. Suggestions were made for the Board to have a link to the Maryland Register, references to other sites, advertise for pharmacists to reciprocate from other states and to publicize our Y2K statement.

Questions for the Board

Policy on Sale of Syringes -

Rite Aid of Maryland, Inc. has developed a written policy on the dispensing of needles and syringes or other paraphernalia, which they have presented to the Board for its approval. Dr. Love motioned to send a letter advising Rite Aid that their policy must be consistent with current state regulations. The motion was seconded by Ms. Furman, with a unanimous decision from the Board. Ms. Andoll will draft a letter to that effect.

Informational

Emergency Action on Regulations -

Ms. Pease stated that the emergency regulations from the Board of Physician Quality Assurance (BPQA), give Physician Assistants the authority to prescribe medication under certain conditions. These regulations have become finalized as emergency regulations. Ms. Pease stated that the Board of Physicians is in the process of promulgating these regulations. Dr. Love motioned for the Board to ask for a joint meeting with representatives from the BPQA to discuss how Physician Assistants prescriptive authority can be implemented by pharmacists. The motion was seconded by Ms. Hawkins, with a unanimous decision from the Board. Dr. Love suggested Ms. Andoll, Mr. Schiff and Mr. Rubin be a part of this meeting.

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Follow - Up Letters/Meetings

PDX Prescription Transfer System -

Already been voted on and approved at August 1999 Board meeting.

Meeting adjourned at 11:52 A.M.

Respectively Submitted,

W. Irving Lottier, Jr.
Secretary